

510(k) Summary

K092842

Submitted by: INDEC Systems, Inc.
2210 Martin Ave.
Santa Clara, CA 95050

MAR - 1 2010

Tel: 408-986-1600
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Contact Person: Carol Hubler
Date: September 14, 2009

Device Trade Name: echoPlaque
Common Name: echoPlaque Intra Vascular Analysis Software
Classification: Picture Archiving and Communication System, Class II
Sec. 21 CFR 807.92

Predicate Devices:

QIVA Intra Vascular Ultrasound Analysis software (K021495)
QCU-CMS Analytical Software Package (K011582)

Description of the Device:

echoPlaque is a software product that provides capabilities for loading, acquiring, viewing, analyzing and saving vendor-neutral, multi-frame DICOM data from Intravascular Ultrasound (IVUS) studies, INDEC echoPlaque IMG/BMG IVUS files, and medical datasets saved as Microsoft Video 1 codec compressed AVI files. **echoPlaque's** main functionality includes viewing and playback of medical images and ancillary files, acquiring new images from analog and digital signals, image analysis including 2D and volumetric measurements, and the ability to resave multi-frame images in either a compressed or uncompressed format for future visualization and analysis.

Intended Use of the Device:

echoPlaque is a software product intended to be used to review, analyze, and measure intravascular ultrasound (IVUS) images. **echoPlaque** is intended to help qualified medical professionals examine intravascular ultrasound (IVUS) images and make measurements to quantify vessel and stent dimensions. These features aid in post-procedure analysis regarding the placement of interventional devices.

Substantial Equivalence to Predicate Device:

echoPlaque 3.0 is substantially equivalent in intended use, design, and operation characteristics to the following currently marketed devices:

- QIVA Intra Vascular Ultrasound Analysis software (K021495)
- Medis Medical Imaging Systems B.V. QCU-CMS Analytical Software Package (K011582)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Carol Hubler
Vice President
Indec Systems, Inc.
2210 Martin Ave.
SANTA CLARA CA 95050

MAR - 1 2010

Re: K092842

Trade/Device Name: echoPlaque
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: January 22, 2010
Received: January 26, 2010

Dear Ms. Hubler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

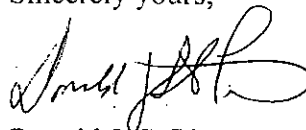
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Donald J. St. Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: echoPlaque

Indications for Use:

echoPlaque is a software product intended to be used to visualize, analyze, and save DICOM and IMG/BMG (INDEC proprietary format) Intravascular Ultrasound (IVUS) images. echoPlaque is intended to allow qualified medical professionals to view, measure, and save new IVUS images. Images can be loaded into the echoPlaque software via removable media (CD/DVD) or hard disk or new images can be acquired from an analog or digital video signal. echoPlaque supports linear, area, and volumetric measurements. Measurements can be exported and images can be saved using echoPlaque. Images can be saved in either a compressed or uncompressed format. These features aid in post-procedure analysis regarding the placement of interventional devices.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER
PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature]

(Division Sign-Off)

Division of Radiological Devices

Office of *In Vitro* Diagnostic Device Evaluation and Safety

510(k) Number

K092842

(Posted November 13, 2003)